

Losartan / Amlodipine Besylate Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 49944-00023 Date of last issue: 30.09.2023
Date of first issue: 26.01.2015

Section 1: Identification

Product identifier : Losartan / Amlodipine Besylate Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable


Manufacturer or supplier's details

Company : Organon & Co.
Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302
Telephone : +1-551-430-6000
Emergency telephone number : +1-215-631-6999
E-mail address : EHSSTEWARD@organon.com

Section 2: Hazard identification**Classification of the substance or mixture**

Serious eye damage/eye irritation : Category 1
Skin sensitisation : Category 1
Reproductive toxicity : Category 1B
Effects on or via lactation
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Blood, Cardio-vascular system, Stomach, Kidney)

GHS Label elements, including precautionary statements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H360D May damage the unborn child.
H362 May cause harm to breast-fed children.

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H373 May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated exposure if swallowed.

Precautionary statements :

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------------|-------------|-----------------------|
| Cellulose | 9004-34-6 | >= 50 -< 70 |
| Losartan | 124750-99-8 | >= 10 -< 20 |
| Amlodipine Besylate | 652969-01-2 | >= 1 -< 2.5 |
| Titanium dioxide | 13463-67-7 | >= 0.1 -< 1 |

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Section 4: First-aid measures**Description of necessary first-aid measures**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

- Risks : May cause an allergic skin reaction.
Causes serious eye damage.
May damage the unborn child.
May cause harm to breast-fed children.
May cause damage to organs through prolonged or repeated exposure if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
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Section 5: Fire-fighting measures**Extinguishing media**

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.

Special hazards arising from the substance or mixture

- Specific hazards during fire- : Avoid generating dust; fine dust dispersed in air in sufficient

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fighting concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
Metal oxides

Special protective actions for fire-fighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Section 6: Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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Section 7: Handling and storage**Precautions for safe handling**

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Avoid contact during pregnancy and while nursing.
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.

Conditions for safe storage, including any incompatibilities

- Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Section 8: Exposure controls/personal protection**Control parameters****Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of | Control parameters / Permissible | Basis |
|------------|---------|------------------------|----------------------------------|-------|
|------------|---------|------------------------|----------------------------------|-------|

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| | | exposure) | concentration | |
|---------------------|-------------|-----------------|-------------------------------|----------|
| Cellulose | 9004-34-6 | PEL (long term) | 10 mg/m ³ | SG OEL |
| | | TWA | 10 mg/m ³ | ACGIH |
| Losartan | 124750-99-8 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| Amlodipine Besylate | 652969-01-2 | TWA | 20 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |
| Titanium dioxide | 13463-67-7 | PEL (long term) | 10 mg/m ³ | SG OEL |

Appropriate engineering control measures : Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection : Wear the following personal protective equipment:
Chemical resistant goggles must be worn.
If splashes are likely to occur, wear:
Face-shield

Skin protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Section 9: Physical and chemical properties

Appearance : powder

Colour : No data available

SAFETY DATA SHEET



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| | | |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | Not applicable |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |

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Molecular weight : No data available

Particle characteristics
Particle size : No data available

Section 10: Stability and reactivity

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| Reactivity | : Not classified as a reactivity hazard. |
| Chemical stability | : Stable under normal conditions. |
| Possibility of hazardous reactions | : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. |
| Conditions to avoid | : Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : Oxidizing agents |
| Hazardous decomposition products | : No hazardous decomposition products are known. |

Section 11: Toxicological information

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgement

Components:
Cellulose:

| | |
|---------------------------|------------------------------------------------------------------------------|
| Acute oral toxicity | : LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : LD50 (Rabbit): > 2,000 mg/kg |

Losartan:

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| Acute oral toxicity | : LD50 (Mouse): 1,257 - 1,590 mg/kg LDLo (Rat): 200 mg/kg LDLo (Mouse): 400 mg/kg |
|---------------------|-----------------------------------------------------------------------------------------|

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Amlodipine Besylate:

|| Acute oral toxicity : LD50 (Rat): 393 mg/kg

Titanium dioxide:

|| Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

|| Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity**Skin corrosion/irritation**

Not classified based on available information.

Components:**Losartan:**|| Species : Rabbit
|| Result : Mild skin irritation**Titanium dioxide:**|| Species : Rabbit
|| Result : No skin irritation**Serious eye damage/eye irritation**

Causes serious eye damage.

Components:**Losartan:**|| Species : Rabbit
|| Result : Severe irritation**Amlodipine Besylate:**|| Species : Rabbit
|| Result : Severe irritation**Titanium dioxide:**|| Species : Rabbit
|| Result : No eye irritation**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

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Respiratory sensitisation

Not classified based on available information.

Components:**Losartan:**

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|-----------------|-----------------------------------------------------------|
| Test Type | : Maximisation Test |
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Assessment | : Probability or evidence of skin sensitisation in humans |
| Result | : positive |

Titanium dioxide:

| | |
|-----------------|---------------------------------|
| Test Type | : Local lymph node assay (LLNA) |
| Exposure routes | : Skin contact |
| Species | : Mouse |
| Result | : negative |

Germ cell mutagenicity

Not classified based on available information.

Components:**Cellulose:**

| | |
|-----------------------|----------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) |
| | Result: negative |
| Genotoxicity in vivo | : Test Type: In vitro mammalian cell gene mutation test |
| | Result: negative |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) |
| | Species: Mouse |
| | Application Route: Ingestion |
| | Result: negative |

Losartan:

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|-----------------------|---------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: in vitro assay |
| | Result: negative |
| | : Test Type: In vitro mammalian cell gene mutation test |
| Genotoxicity in vivo | : Test system: Chinese hamster ovary cells |
| | Result: negative |
| | : Test Type: Alkaline elution assay |
| Genotoxicity in vivo | : Result: negative |
| | : Test Type: Chromosomal aberration |
| | Result: negative |

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Result: negative

Amlodipine Besylate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Titanium dioxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Cellulose:**

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Losartan:

Species : Mouse
Application Route : Oral
Exposure time : 92 weeks
Dose : 200 mg/kg body weight
Result : negative

Species : Rat
Application Route : Oral
Exposure time : 105 weeks
Dose : 270 mg/kg body weight
Result : negative

Amlodipine Besylate:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : Oral

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| | |
|---------------|------------|
| Exposure time | : 2 Years |
| Result | : negative |

Titanium dioxide:

| | |
|-------------------|------------------------------------------------------------------|
| Species | : Rat |
| Application Route | : inhalation (dust/mist/fume) |
| Exposure time | : 2 Years |
| Method | : OECD Test Guideline 453 |
| Result | : positive |
| Remarks | : The mechanism or mode of action may not be relevant in humans. |

| | |
|------------------------------|---------------------------------------------------------------------------|
| Carcinogenicity - Assessment | : Limited evidence of carcinogenicity in inhalation studies with animals. |
|------------------------------|---------------------------------------------------------------------------|

Reproductive toxicity

May damage the unborn child.
May cause harm to breast-fed children.

Components:**Cellulose:**

| | |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative |
| Effects on foetal development | : Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative |

Losartan:

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|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : Test Type: Fertility Species: Rat, female Application Route: Oral Fertility: LOAEL: 200 mg/kg body weight Result: female reproductive effects Remarks: Maternal toxicity observed. |
| Effects on foetal development | : Test Type: Development Species: Rabbit Application Route: Oral General Toxicity Maternal: NOAEL: 10 mg/kg body weight Developmental Toxicity: NOAEL F1: 20 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects |
| | Test Type: Development Species: Rat |

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| Reproductive toxicity - Assessment | : Application Route: Oral Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: Fetotoxicity, No teratogenic effects |
| | : Clear evidence of adverse effects on development, based on animal experiments. |
| | : Studies indicating a hazard to babies during the lactation period |

Amlodipine Besylate:

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| Effects on fertility | : Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Fertility: NOAEL: 10 mg/kg body weight Result: No effects on fertility |
| | : Test Type: Fertility/early embryonic development Species: Rabbit Application Route: Ingestion Fertility: NOAEL: 25 mg/kg body weight Result: No effects on fertility |
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: Effects on foetal development |
| | : Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: No effects on foetal development |
| | : Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Developmental Toxicity: LOAEL: 1.6 mg/kg body weight Result: Effects on foetal development Remarks: Maternal toxicity observed. |

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated exposure if swallowed.

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Components:**Losartan:**

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| Exposure routes | : Ingestion |
| Target Organs | : Blood, Cardio-vascular system, Stomach, Kidney |
| Assessment | : May cause damage to organs through prolonged or repeated exposure. |

Repeated dose toxicity**Components:****Cellulose:**

| | |
|-------------------|------------------|
| Species | : Rat |
| NOAEL | : >= 9,000 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 90 Days |

Losartan:

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|---------------------|--------------------------------------------------|
| Species | : Rat |
| LOAEL | : 15 mg/kg |
| Application Route | : Oral |
| Exposure time | : 309 d |
| Number of exposures | : daily |
| Target Organs | : Blood, Kidney, Cardio-vascular system, Stomach |

| | |
|-------------------|------------------------|
| Species | : Dog |
| NOAEL | : 5 mg/kg |
| Application Route | : Oral |
| Exposure time | : 1 Months |
| Symptoms | : Salivation, Vomiting |

| | |
|---------------------|------------------------|
| Species | : Dog |
| LOAEL | : 25 mg/kg |
| Application Route | : Oral |
| Exposure time | : 53 Weeks |
| Number of exposures | : daily |
| Symptoms | : Salivation, Vomiting |

Amlodipine Besylate:

| | |
|-------------------|------------------------------------------------|
| Species | : Rat |
| NOAEL | : 15 mg/kg |
| Application Route | : Oral |
| Exposure time | : 90 d |
| Remarks | : No significant adverse effects were reported |

Titanium dioxide:

| | |
|-------------------|----------------|
| Species | : Rat |
| NOAEL | : 24,000 mg/kg |
| Application Route | : Ingestion |

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| | | |
|-------------------|---|-----------------------------|
| Exposure time | : | 28 Days |
| Species | : | Rat |
| NOAEL | : | 10 mg/m ³ |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 2 yr |

Aspiration toxicity

Not classified based on available information.

Components:**Losartan:**

No aspiration toxicity classification

Experience with human exposure**Components:****Losartan:**

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|-------------|---|------------------------------------|
| Eye contact | : | Symptoms: Eye irritation |
| Ingestion | : | Symptoms: hypotension, tachycardia |

Amlodipine Besylate:

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| Eye contact | : | Symptoms: Severe irritation |
| Ingestion | : | Symptoms: Nausea, Abdominal pain, Fatigue, Headache, Oedema, Palpitation |

Section 12: Ecological information**Toxicity****Components:****Cellulose:**

| | | |
|------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish | : | LC ₅₀ (<i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials |
|------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------|

Losartan:

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| Toxicity to fish | : | LC ₅₀ (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 929 mg/l Exposure time: 96 h Method: FDA 4.11 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC ₅₀ (<i>Daphnia magna</i> (Water flea)): 331 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | NOEC (<i>Microcystis aeruginosa</i> (blue-green algae)): 949 mg/l Exposure time: 10 d Method: FDA 4.01 |

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| | NOEC (<i>Selenastrum capricornutum</i> (green algae)): 143 mg/l Exposure time: 10 d Method: FDA 4.01 |
| Toxicity to fish (Chronic toxicity) | : NOEC (<i>Pimephales promelas</i> (fathead minnow)): 10 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (<i>Daphnia magna</i> (Water flea)): 100 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 |

Amlodipine Besylate:

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|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish | : LC50 (<i>Pimephales promelas</i> (fathead minnow)): 2.7 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (<i>Daphnia magna</i> (Water flea)): 3.2 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : IC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): 5.6 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |

Titanium dioxide:

| | |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish | : LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (<i>Daphnia magna</i> (Water flea)): > 100 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : EC50 (<i>Skeletonema costatum</i> (marine diatom)): > 10,000 mg/l Exposure time: 72 h |
| Toxicity to microorganisms | : EC50: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 |

Persistence and degradability**Components:****Cellulose:**

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| Biodegradability | : Result: Readily biodegradable. |
|------------------|----------------------------------|

Losartan:

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| Stability in water | : Hydrolysis: < 10 % (5 d) |
|--------------------|----------------------------|

Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 30.09.2023 |
| 5.0 | 06.04.2024 | 49944-00023 | Date of first issue: 26.01.2015 |

Bioaccumulative potential**Components:****Losartan:**

| | | |
|----------------------------------------|---|--------------|
| Partition coefficient: n-octanol/water | : | log Pow: 1.2 |
|----------------------------------------|---|--------------|

Amlodipine Besylate:

| | | |
|----------------------------------------|---|------------|
| Partition coefficient: n-octanol/water | : | log Pow: 3 |
|----------------------------------------|---|------------|

Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

| | | |
|------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waste from residues | : | Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

Section 14: Transport information**International Regulations****UNRTDG**

| | | |
|----------------------------|---|----------------|
| UN number | : | Not applicable |
| UN proper shipping name | : | Not applicable |
| Transport hazard class(es) | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Environmentally hazardous | : | no |

IATA-DGR

| | | |
|------------------------------------------|---|----------------|
| UN/ID No. | : | Not applicable |
| UN proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Packing instruction (cargo aircraft) | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

IMDG-Code

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UN number : Not applicable
UN proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

Section 15: Regulatory information**Safety, health and environmental regulations specific for the product in question**

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable
Regulations

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 06.04.2024

Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
compile the Safety Data eChem Portal search results and European Chemicals Agen-
Sheet cy, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

Full text of other abbreviations

Losartan / Amlodipine Besylate Formulation

| | | | |
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ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average
 SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN